FIRST SEMESTER

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SECOND SEMESTER

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THIRD AND FOURTH SEMESTER

Research Work for one year
The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under:
Evaluation of written thesis : MM 200
Presentation of seminar on thesis : MM 100
and viva-voce
Total : 300 marks

[Note : Credit System : 1 credit = 20 marks, L- Lecture – Tutorial, P – Practical]
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Module 01 and Module 02

Separation Techniques:
Chromatography general Principles, Classification, Chromatographic techniques, normal and reversed phase, column chromatography, TLC, counter current chromatography, droplet chromatography, Ion exchange chromatography.

Gas Chromatography:
Theory & Principles, column operation, instrumentation and Applications in Pharmaceutical analysis.

High Performance liquid Chromatography:
Theory and Principle, column operation instrumentation and application in Pharmaceutical analysis.

Module 03

Electrometric methods of analysis:
Principle, Procedure of Pharmaceutical applications of Conductometric titrations, Amperometric titrations and Controlled potential electrolysis

Module 04

Light scattering methods in quantitative analysis
Nephelometry and Turbidometry
Quantitative analysis based on molecular luminescence:
Flourimetry and Phosphorimetry

Module 05

Statistical Analysis Methods
Probability: Introduction, Definition, Importance of the concept of probability, Experiments & Events, Mutually exclusive events, Independent & Dependent events, exhaustive events, complementary events, theoremson Probability, conditional probability, binomial distribution and poison distribution.

Module 06

Correlation:
Introduction, significance, Types of correlation, Karl Pearson’s coefficient of correlation, Rank correlation, merits & limits of the Rank Method.

Regression:
Introduction, Regression equation of Y on X and Regression equation of X on Y.

Chi square:
Introduction, definition, conditions for applying chi square & uses of chi square.

F-Test:
Assumptions and Applications.

ANOVA:
Assumptions, Techniques of Analysis of variance. (one way & two way)

Calculation of ED_{50}, LD_{50} & Probit analysis
Reading Material Recommended
Module 01
**Ultraviolet and Visible spectroscopy**:  
Introduction, energy levels, selection rules; Woodward Fieser, Fieser Kuhn and Nelson rule, Influence of substituents, ring size and strain on spectra characteristics, solvent effect, methodology, spectral correlation with structure.

Module 02
**Infrared Spectroscopy**:  
Introduction, types of vibrations, characteristics regions of the spectrum, influence of substituents, ring size, hydrogen bonding, vibrational coupling, field effects on frequency, methodology, spectral interpretation with example.

Module 03 and 04
**Nuclear Magnetic Resonance spectroscopy**:  
Introduction, magnetic nuclear, chemical shift, shielding, relaxation process, chemical & magnetic non equivalence, local dia magnetic shielding and magnetic anisotropy, spin splitting, Pascal triangle, coupling constant, mechanism of coupling, quadrupole broadening and decoupling. Effect of stereochemistry on the spectrum, shift reagent, application of $^1$HNMR with some examples. Introduction to the following techniques would be covered DEPT, APT, COSY, NOESY and INADEQUATE.

Module 05 and 06
**Mass Spectrometry**:  
Introduction, Essential components of a mass spectrometer, types of ions, molecular ion, fragment ion, rearrangement ion, metastable ion, Isotopic ions and their corresponding peaks, rules of fragmentation Mc Lafferty rearrangement, Retro Diels Alder and other fragmentation patterns. Introduction to FAB, LC-MS, and GC-MS.

Reading Material Recommended

Module 01

Atomic Absorption Spectroscopy:

Module 02 and Module 03

$^{13}$C Nuclear Magnetic Resonance ($^{13}$C – NMR):
Natural abundance of $^{13}$C, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift, Effect of substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and $^{13}$C-$^1$H coupling

Module 04

ESR:
Principle and correlation with proton magnetic resonance, derivative curves, g-values, hyperfine splitting, Applications.

Module 05

Raman Spectroscopy:
Introduction, Principle and application of Raman Spectroscopy.

Module 06

Flame Photometry:
Introduction, Instrumentation, Effect of Solvent in Flame Photometry, Applications of Flame Photometry, Interferences in Flame Photometry and Limitations of Flame Photometry

Reading Material Recommended
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1. Interpretation of spectra of organic compounds- Workshop involving interpretation of IR, NMR and Mass spectra of Organic compounds to elucidate their chemical structure.
2. Basic chromatographic techniques
3. Experiments Based on HPLC and GC
5. Use of spectrophotometer for analysis for pharmaceutical compounds & their formulations.
M.PHARMACY (Pharm. Analysis)- SEMESTER II

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<td>1</td>
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**Module 01**
Detection and quantitative determine of preservatives antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulations.

**Module 02**
Principles and Procedures involving the use of the following regents in the Pharmaceutical analysis with suitable examples.
- MBTH reagent
- FC (folin-ciocalteu) reagents
- PDAB reagent
- Ninhydrin reagent
- Carr-price reagent
- PDAC reagent
- 2,4-DNP.

**Module 03**
Principle & Procedure involved in quantitative determine of the following functional groups: hydroxyl, carboxyl, aldehyde, Ketone, methoxyl, ester, amine

**Module 04 and 05**
Principle & Procedure involved in the analysis of Preparations & dosage forms containing.
- Alkaloids: Cinchona, Ergot
- Glycosides: Digitoxin & Digoxin
- Vitamins: Vitamin A, B₁, B₂, B₁₂, and C
- Steroids: Esterogen, Androgens and cholesterol
- sulphonamides.

**Module 06**
Validation of analysis methods, calibration of instruments & equipments, quality assurance & raw materials. Elemental analysis such as determine of Na, K, Ca, P₄, S₈,Cl₂.

**Reading Material Recommended**
1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
6. P D Sethi Quantitative Analysis of Drugs in Pharmaceutical formulations
7. Howard C.Ansel, Michelle J. Stoklosa, Lippincott Williams & Wilkins, Pharmaceutical Calculations.
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**Module 01**
Detailed study of principles & procedures involved in bio assay of. Heparin, insulin, posterior pituitary, Diphtheria, typhoid

**Module 02**
Principles and Procedures involved in Biological tests of the following.
- Living contaminants in vaccines.
- Absence of Pyrogens.
- Histamine like substances
- Determine of toxic elements

**Module 03**
Study of method procedure, drugs of formulations standard requirements of herbal medicines, traditional and folk remedies, preparation & their quality, safety and efficacy assessment & use for acceptance by FDA.

**Module 04**
Radioimmuno assay: Gen principles, scope of limitations R.I.A of Insulin and digitalis.
Introduction to Bio equivalence studies & their importance.

**Module 05**
Thermal Methods of Analysis:
Theory, Instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

**Module 06**
Various types of raw material used in the cosmetic industry for the manufacture of finished products.
General method of analysis to determine the quality of raw materials used in cosmetic industry.

**Reading Material Recommended**
1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
6. British Pharmacopeia, Department of Health U.K.
7. Classification of cosmetic raw materials and adjuncts IS 3958 of Indian standards institution (BIS).
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**Module 01 and Module 02**

**Drug Regulatory Affairs:**
Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

**Module 03**

**Stability Testing:**
Role of stability testing, stability test guidelines. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, determination of shelf life. Stability test equipment and recent developments in this area.

**Module 04**

**Documentation:**
Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.

**Module 05**

**GMP of Pharmaceuticals:**
Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

**Module 06**

**Good Laboratory Practice:**

**Reading Material Recommended**

2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, Vth edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. [http://www.patentinoffice.nic.in](http://www.patentinoffice.nic.in)
4. [http://www.patentmatics.com](http://www.patentmatics.com)
5. [http://www.iprlawindia.org](http://www.iprlawindia.org)
6. [http://www.indianpatent.org.in](http://www.indianpatent.org.in)
7. [http://www.wipo.int](http://www.wipo.int)
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1. Assay of calcium gluconate
2. Assay of amoxicillin
3. Assay of Phenylhydrazine HCl
4. Assay of frusemide tablets
5. Assay of Lignocaine HCl injection
6. Assay of vitamin B₁₂/folic acid in vitamin preparations
7. Estimation of cotrimazole tablets
8. Determination of hardness of water
9. Drug analysis by U.V.& I.R
10. Analysis of Drugs in blood & urine sample
11. Estimation of Quinine Sulphate
12. Assay of rifampicin
14. IR, NMR, Graphs interpretation
15. Based on topic covered in theory with emphasis on analysis of cosmetics and their adulteration with reference to Drugs and Cosmetic rules 1945.
16. Quality control tests for some cosmetics.